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Flemming Kjaergaard Christensen

PATRADE

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EXAMINER

MI, QIUWEN

ART UNIT

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1655

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10/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,976	<b>Applicant(s)</b> CHRISTENSEN, FLEMMING KJAERGAARD	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment in the reply filed on 10/5/2010 is acknowledged. Claims 2 and 3 are cancelled. Claims 1, and 4-20 are pending. Claims 6, and 8-10 are withdrawn. **Claims 1, 4, 5, 7, and 11-20 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

It is noted that the correct status of claims 6, 8, and 9 should be "Currently amended, Withdrawn).

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, and 11-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita (JP 06128121 A), in view of Dupont et al (US 6,028,118).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/5/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Yamashita teaches cosmetic preparations that contain Aspalathus linearis extract as active ingredient and have the effect of providing moisture to the skin and hair and preventing skin

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aging [0001]. Yamashita also teaches as a result of further research, the inventor found that the application of a cosmetic preparation containing an *Aspalathus linearis* extract to the skin has effects against skin aging, such as wrinkling, pigmentation, and so forth, caused by ultraviolet radiation, and its application to the hair (thus a topical administration to the scalp) does not make the hair sticky and, moreover, has the effect of enhancing the hair-moisturizing effect [0004].

Yamashita further teaches the cosmetic preparation of the present invention is prepared by blending the aforesaid active ingredient in a known formulation that is acceptable for the skin or hair application, and its blending quantity is usually from 0.001 to 30.0% by weight, preferably from 0.01 to 20% by weight (thus overlaps with the claimed range of 1-20%, 1%. 2-12%, 3-10%, 5-8%, 1-3%), of the cosmetic preparation as a whole. Yamashita teaches as noted earlier, the known formulation of the cosmetic composition means any formulation that can be applied externally, and some examples thereof includes, as skin-use preparations, cataplasm, plaster, paste (thus a medicament), cream, ointment (thus a medicament), aerosol, emulsion, lotion, milky lotion, essence, pack, gel, powder, foundation, suncare, bath salt, soap, and so forth and, as hair-use preparation, shampoo (thus a topical administration to the scalp), rinse, hair tonic, hair liquid, hair spray, hair form, and so forth [0010]. Yamashita also teaches a composition containing an ancillary agent purified water (page 11, [0028]).

Yamashita does not teach the incorporation of the extract of deep-sea fish.

Dupont et al teach a method for regulating wrinkles or atrophy in mammalian skin, said method comprising the step of applying to the skin a therapeutically effective amount of a shark cartilage extract (thus a deep sea fish extract that comprising protein) obtained by a process comprising the steps of: a) homogenizing shark cartilage in an aqueous solution in conditions

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which are substantially non-denaturing towards biologically active components extracted from cartilage, until the cartilage is reduced to solid particles whose size is lower than or equal to about 500  $\mu\text{m}$ ; b) extracting said biologically active components into said aqueous solution, which results in a mixture of solid particles and of crude liquid extract having said biological active components; c) separating said crude liquid extract from said solid particles; and d) further separating the crude liquid extract so as to obtain a final liquid extract containing cartilage molecules having a molecular weight lower than about 500 Kilodaltons (KDa) (claim 8). Dupont et al teach a method for retarding premature aging in mammalian skin, said method comprising the step of applying to the skin a therapeutically effective amount of a shark cartilage extract obtained by the same mentioned process (claim 11). Dupont et al also teach Collagenase and inflammation are linked to premature aging (degradation of collagen), and therefore the antagonist activities recovered in the cartilage extract could also be put to contribution in compositions and methods for retarding premature aging, and for regulating wrinkles or atrophy in mammalian skin. As causes of wrinkles or atrophy are listed, by way of examples, age, exposure to ultraviolet radiation or to environmental pollutant. Topical compositions may comprise an effective amount of shark cartilage, to be determined for each specific application. In general, these compositions may contain from about 0.1 to about 75 weight percent of a liquid cartilage extract (thus comprising protein, thus overlaps with the claimed range of 0.25-2.0%) and from about 25 to 99.9 weight percent of a pharmaceutically acceptable vehicle (thus a filler or ancillary agent). These compositions may contain an anti-oxidant such as an agent which prevents the formation of lipid peroxides in skin. Examples of such anti-oxidant are tocopherol, tocopherol derivatives, ascorbic acid, ascorbic acid derivatives and BHT. Topical compositions

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may take diverse forms such as solutions, suspensions, lotions, tinctures, gels, creams, sprays, emulsions, sticks, ointments or liposomes (at least a portion of the liquid cartilage extract being present in liposomes) (col 35, lines 11-36).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the shark cartilage extract from Dupont et al et al since Dupont et al teach the shark cartilage extract can regulating wrinkles and retarding premature aging. Therefore, it would have been obvious for one of the ordinary skills in the art to incorporate the deep sea extract fish extract shark cartilage from Dupont et al to enhance the effects of Yamashita composition in against skin aging, such as wrinkling and pigmentation.

Since both of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Neither Dupont nor Yamashita described, suggested or would have made obvious a combination of the two liquid extracts” (page 5, 4<sup>th</sup> paragraph from the bottom).

In response to applicant’s argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the shark cartilage extract from Dupont et al et al since Dupont et al teach the shark cartilage extract can regulating wrinkles and retarding premature aging. Therefore, it would have been obvious for one of the ordinary skills in the art to incorporate the deep sea extract fish extract shark cartilage from Dupont et al to enhance the effects of Yamashita composition in against skin aging, such as wrinkling and pigmentation.

Applicant argues that “In contrast, the present invention describes obtaining powders [0024] from "a solid fraction (SOLID EXTRACT)" that Dupont mentions but does not use and specifically excludes from use” (page 5, 3<sup>rd</sup> paragraph from the bottom) Applicant also argues that “In further contrast, the present invention described using Rooibos (*Aspalathus Linearis*) powder [0027] Herbasec MPE Rooibus” (page 5, 2nd paragraph from the bottom).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a solid fraction (SOLID EXTRACT)" or “Herbasec MPE Rooibus”) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Applicant argues that “In contrast, Dupont and Yamashita each uses only one active ingredient extract. The percentage ranges described in claim 1 and 18 are not described in or suggested by the references. Claim 19 *points* out that the percentage of deep sea fish extract is about 24%. That is not suggested or made obvious by Dupont. Claim 20 point out that the percentage of rooibus extract is about 1.40%. That is not suggested or made obvious by Yamashita” (page 6, 2<sup>nd</sup>-5<sup>th</sup> paragraph).

This is not found persuasive. All the claim limitations are met, please see the above rejection for details.

Claims 1, 4, 7, and 11-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita and Dupont et al as applied to claims 1, 7, and 11-20 above, and further in view of Shibata et al (JP 08310939 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/5/2010, repeated below. Applicants’ arguments filed have been fully considered but they are not deemed to be persuasive.

The teachings of Yamashita and Dupont et al are set forth above and applied as before.

The combination of Yamashita and Dupont et al do not specifically teach the incorporation of horsetail extract into the composition.

Shibata et al teach external fair-skin preparation contains extract of Equisetae family, Equisetum genus particularly Equisetum arvense L., Equisetum hyemale L. or Equisetum debile Roxb., at concentration of 0.05-20.0 wt.%, excluding Equisetum giganteum. Raw materials are extracted with conventional solvent (e.g. MeOH, EtOH, aqueous alcohols, acetone and EtOAc)



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and resultant extract is added to conventional external preparation bases including cosmetics together with known additives and carriers. It is used to prevent and treat pigmentation, spots, freckles and chloasma at concentration of 0.005-20.0 (preferably 0.01-10.0) wt.% in external composition. Composition is non-toxic. In an example, extracts of *Equisetum arvense* L., *Equisetum myemale* L. and *Equisetum debile* Roxb inhibited melanin formation at concentration of 0.01 wt.% in cultured B16 melanoma cells. At same concentration, these extracts inhibited tyrosinase activity at rate of 98, 97 and 98%, respectively (see Abstract, the rejection is based on the Abstract, full translation was attached in the last office action).

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use extracts of *Equisetum arvense* from Shibata et al since Shibata et al teach it is used to prevent and treat pigmentation, spots, freckles and chloasma. Therefore, it would also have been obvious one of ordinary skill in the art to incorporate the extracts of *Equisetum arvense* from Shibata into the composition of Yamashita to enhance the antiaging effect such as pigmentation.

Since all of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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Applicant argues that “Claim 4 adds to the new and unobvious combination of claim 1 a horsetail extract, a shellfish extract or both. Nothing in the prior art suggests or would have made obvious the combining of those three extract. Shibata describes using an *Equisetum arvense* L extract, but does not suggest or make obvious the use of that extract with any other extract or a combination of extract” (page 6, paragraphs 6-8).

This is not found persuasive. As stated above, It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use extracts of *Equisetum arvense* from Shibata et al since Shibata et al teach it is used to prevent and treat pigmentation, spots, freckles and chloasma. Therefore, it would also have been obvious one of ordinary skill in the art to incorporate the extracts of *Equisetum arvense* from Shibata into the composition of Yamashita to enhance the antiaging effect such as pigmentation. Since all of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

Claims 1, 5, 7, and 11-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita and Dupont et al as applied to claims 1, 7, and 11-20 above, and further in view of Honda et al (JP 2003055190 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/5/2010, repeated below. Applicants’ arguments filed have been fully considered but they are not deemed to be persuasive.

The teachings of Yamashita and Dupont et al are set forth above and applied as before.

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The combination of Yamashita and Dupont et al do not specifically teach the incorporation of diacetyl boldine into the composition.

Honda et al teach a collagenase inhibitor which has an excellent collagenase activity-inhibiting action and can prevent and improve the ageing of skin, and to prepare an anti-ageing cosmetic. The collagenase inhibitor contains a solvent extract of a plant selected from *Peumus boldus* Morina, etc., as an active ingredient. The anti-ageing cosmetic contains the collagenase inhibitor (see Abstract). Honda et al also teach extracting *Peumus boldus* with solvent such as water, methanol, and ethanol ([0013])(thus the extract of *Peumus boldus* necessarily contains diacetyl boldine (see the machine translation attached).

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the *Peumus boldus* extract that contains diacetyl boldine from Honda et al since Honda et al teach the extract of *Peumus boldus* contains collagenase inhibitor that could improve ageing of skin. Therefore, it would have been obvious for one of the ordinary skills in the art to incorporate the *Peumus boldus* extract that contains diacetyl boldine to enhance the antiaging effect of Yamashita composition.

Since all of the compositions yielded beneficial results in anti-skin aging cosmetic industry, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Claim 5 distinguishes and would not have been obvious from the references. Claim 5 adds diacetyl boldine to the new and unobvious combined extract in claim I. Honda has been cited for diacetyl boldine. However, neither the Honda translation nor the one page machine translation mentions diacetyl boldine. Even if Honda has mentioned diacetyl boldine, that would not have suggested or made obvious the combination of diacetyl boldine with the new and unobvious combination pointed out in claim 1” (page 6, last two paragraphs bridging page 7).

This is not found persuasive. Honda et al teach extracting *Peumus boldus* with solvent such as water, methanol, and ethanol ([0013], thus the extract of *Peumus boldus* necessarily contains diacetyl boldine. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the *Peumus boldus* extract that contains diacetyl boldine from Honda et al since Honda et al teach the extract of *Peumus boldus* contains collagenase inhibitor that could improve ageing of skin. Therefore, it would have been obvious for one of the ordinary skills in the art to incorporate the *Peumus boldus* extract that contains diacetyl boldine to enhance the antiaging effect of Yamashita composition.

Applicant argues that “Claim 7 distinguishes and would not have been obvious from the references. Claim 7 points out the topical administration of the composition of claim 1 to the scalp. Nothing in the Dupont and Yamashita references would have suggested the new and unobvious composition of claim I. Nothing in the references would have rendered obvious the application of the new and unobvious composition to the scalp. Yamashita describes applying a

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product to hairs for a humectant effect on hair. Yamashita does not describe application to the scalp. Dupont does not mention scalp” (page 7, paragraphs 2-4).

This is not found persuasive. Yamashita teaches as a result of further research, the inventor found that the application of a cosmetic preparation containing an *Aspalathus linearis* extract to the skin has effects against skin aging, such as wrinkling, pigmentation, and so forth, caused by ultraviolet radiation, and its application to the hair (thus a topical administration to the scalp) does not make the hair sticky and, moreover, has the effect of enhancing the hair-moisturizing effect [0004]. Yamashita teaches as noted earlier, the known formulation of the cosmetic composition means any formulation that can be applied externally, and some examples thereof includes, as hair-use preparation, shampoo (thus a topical administration to the scalp), rinse, hair tonic, hair liquid, hair spray, hair form, and so forth [0010]. It is noted that when the product of Yamashita is used as shampoo, rinse or hair spray, it applies to not only hair, but also scalp. Applicant is reminded that what is being claimed is a product, not a method of use.

It is noted that the limitations of each claims have already been addressed in the rejections above.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

### **Conclusion**

No claim is allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655